IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	)	File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
BARBARA SMITH and GARY SMITH, Plaintiffs, vs. ETHICON, INC., et al., Defendants.	)	No. 2:12-CV-04791

VIDEOTAPED DEPOSITION OF
PETER ZENTHOEFER, M.D.

Cathedral City, California
January 31, 2017

Reported by:
Karen I. Pearson-Bell, R.P.R., C.S.R. NO. 3557

GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph|917.591.5672 fax
deps@golkow.com

APPEARANCES:

For Plaintiffs:
DOYLE LOWTHER, LLP
BY: CHRISTOPHER CANTRELL, ESQ.
4400 NE 77th Avenue
Suite 275
Vancouver, Washington 98662
T: 360.818.9320
E: ccantrell@doylelowther.com

For Defendant:
DRINKER BIDDLE & REATH LLP
BY: MELISSA A. MERK, ESQ.
One Logan Square
Suite 2000
Philadelphia, Pennsylvania 19103-6996
T: 215.988.2700
F: 215.988.2757
E: melissa.merk@dbr.com

ALSO PRESENT:
Darnell Brown - Videographer

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VIDEOTAPED DEPOSITION OF

PETER ZENTHOEFER, M.D., JANUARY 31, 2017

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CATHEDRAL CITY, CALIFORNIA;
TUESDAY, JANUARY 31, 2017; 9:12 A.M.
- - -

MS. MERK: Prior to the deposition, counsel for plaintiffs and counsel for Ethicon discussed that counsel for plaintiffs is not bringing an action based on the TVT-O product, only on Prolift. As a result, my questions today will be limited to the doctor's knowledge of Prolift and much less so as to TVT.

MR. CANTRELL: And that's correct.

(Off the record 9:13 - 9:15.)

THE VIDEOGRAPHER: Good morning. We are now on the record. My name is Darnell Brown, and I am the videographer with Golkow Technologies.

Today's date is January 31st, 2017, and the time is 9:15 a.m. This videoed deposition is being held in Cathedral City, California, in the matter of Smith v. Ethicon for the United States District Court for the Southern District of Virginia. The deponent is Dr. Peter Zenthoefer.

Counsel, please identify yourselves for the record.

MR. CANTRELL: Chris Cantrell from Doyle Lowther on behalf of the plaintiffs.

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MS. MERK: Melissa Merk on behalf of Ethicon and Johnson & Johnson.

THE VIDEOGRAPHER: The court reporter is Karen Bell, who will now swear in the witness.

- - -

PETER ZENTHOEFER, M.D.

- - -

having been duly administered an oath in accordance with the California Code of Civil Procedure Section 2094, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY MS. MERK:

Q. Doctor, can you please introduce yourself for the jury.

A. I am Peter Zenthoefer.

Q. And do you understand that we are here today to talk about your care and treatment of Mrs. Barbara Smith?

A. I do.

Q. Okay. Do you remember Ms. Smith?

A. Just a little bit.

Q. Okay. Did you implant TVT-O and Prolift in

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Ms. Smith?

A. I did.

Q. Did you at any time recommend that Ms. Smith file a lawsuit?

A. No.

Q. Have you ever given the opinion that Prolift is defective?

A. No.

Q. Do you understand that I represent Ethicon and Johnson & Johnson?

A. I do.

Q. And do you understand that this is our only opportunity to speak with you about your care and treatment of Ms. Smith?

A. I do.

Q. Okay. Have we ever spoken before today?

A. We have not.

Q. Other than a few minutes of small talk before we got started, have you and I met or interacted in any other way before today?

A. No, we have not.

Q. Did you speak with anyone from plaintiffs' attorney's office?

A. No, I did not.

Q. Okay. What did you do, if anything, to

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prepare for your deposition today?

A. I read the medical record that was sent to me.

Q. Okay. Anything else?

A. No.

Q. Before we came here today, you had provided a copy of your curriculum vitae in an email.

A. Yes.

MS. MERK: Okay. I'm going to mark this as Exhibit 1, please.

(Zenthoefer Exhibit 1 was marked for identification by the Reporter and is annexed hereto.)

BY MS. MERK:

Q. And is this a copy of your CV?

A. (No response.)

Q. The body of it, anyway?

A. It is.

Q. Okay. Can you please, for the jury, describe your educational background, starting with college.

A. So I attended Oregon State University from 1973 to 1976. I started out in biochemistry, biophysics.

I applied to medical school a year early

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and got accepted, and I attended the Oregon Health Sciences School of Medicine in Portland, Oregon, from '76 to '80.

The Air Force helped me through medical school and, in return, I had to spend some time in the Air Force. So I did my residency in obstetrics and gynecology from 1980 to 1984, and then my service obligation was at Fairchild Air Force Base in Washington, near Spokane, and I was there from 1984 to 1987.

Q. And are you licensed?

A. I have an emeritus license right now.

Q. And what does that mean?

A. That allows me to do volunteer work only. I cannot charge for services.

Q. And in what state or states do you hold that license?

A. In Oregon only.

Q. When did you -- When did your license become an emeritus license?

A. So this -- I just renewed it for the second time. So starting January 1st, 2016, it became an emeritus license. I retired September 2015.

Q. Okay. Before you retired, so during the

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course your career, what state or states did you hold an active license in?
A. The last -- For most of my career, in the State of Oregon. Early on in training, I had a license in California, I had a license in Washington, and also in the State of Washington. But most of the time, especially the latter years, only in Oregon.
Q. And are you Board certified?
A. I was Board certified in obstetrics and gynecology, and I let that expire the end of 2016.
Q. Okay. Do you have any academic or teaching experience?
A. A little bit. The last year before I retired, we were affiliated with the urogynecology training program at the Oregon Health Sciences Center. So we were teaching fellows. They rotated through our Kaiser Medical Center.
Q. Can you also briefly explain your professional career, your practice.
A. So I was trained as an obstetrician/gynecologist, and then, over the years, I developed a special interest in the area of urogynecology. I took a lot of continuing education courses in that area.

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And then, approximately in 2009, I became a full-time urogynecologist at Kaiser Sunnyside. I stopped delivering babies and doing obstetrics, and I did primarily urogynecology.
Q. And did you continue to do primarily urogynecology through 2015?
A. Yes.
Q. Were you a member of any professional organizations?
A. I was a member of AUGS, the American Urogynecology Society. I was also a member of IUGA, the International Urogynecology, I think Association or...[pause].
Q. When did you first learn about pelvic organ prolapse?
A. I think in my training, my residency program. So that would have been 1980.
Q. And is that one of the conditions that you treated?
A. Yes.
Q. And same question for stress urinary incontinence. When did you first learn of it?
A. Probably 1980.
Q. Okay. And is that also one of the conditions that you treated during your practice?

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A. Yes.
Q. Can you approximate for me how many patients you treated for pelvic organ prolapse?
A. Over what period of time?
Q. Throughout your career.
A. That would be difficult because those are such, you know, very common problems, and we saw many, many, many patients with those problems.
Q. Okay. Can you estimate for me what percentage of your practice involved the treatment of pelvic organ prolapse?
A. So beginning in 2009, when I became a full-time urogynecologist at Kaiser Sunnyside, pretty much all of it. I would say, you know, more than 95 percent.
Q. In the time frame of 2005 and 2006, were you starting to develop this interest in urogynecology?
A. I was doing primarily urogynecology. At that time I was still on the call schedule at night and I delivered babies. But during the day, during the workweek, it was primarily urogynecology.
Q. Okay. And so that would have been primarily the treatment of pelvic organ prolapse?
A. Uh-huh.

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Q. I'm sorry. Is that a yes?
A. Yes.
Q. Okay. I should have asked you before. Have you had a deposition taken before?
A. I have.
Q. And that was in another mesh case; correct?
A. You know, I have -- I -- over -- Over my career, I have given a few depositions. Some were -- There was one other mesh case, there was an OB case or two, there was a gynecology case.
Q. Okay. I am not going go through all the instructions for a deposition because I think you are familiar with them. But if from time to time I have to ask you is that a yes, please know I am not trying to be rude; I'm just trying to protect our record.
A. No worries.
Q. Okay.
A. I'm...[pause].
Q. Was Prolift one of the products that you used to treat pelvic organ prolapse?
A. It was.
Q. Are you able to estimate the number of times that you used Prolift to treat pelvic organ prolapse prior to 2006?

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A. I'm not sure how many times we used it prior to 2006.
Q. If you are not able to give a number, can you tell me approximately how often you had used it?
A. I know we were using it in 2005 already, and -- and we were using it quite a bit. There were -- At Kaiser Sunnyside there were four urogynecologists, and three of us, you know, started using it a fair amount.
Q. Is it fair to say that by 2006 it was a product that you were comfortable with?
A. Yes.
Q. And that you were familiar with?
A. I think so, yes.
Q. Can you estimate the number of patients that you used Prolip -- Pro -- I'm going to do it again. Try it one more time.
Can you estimate the number of patients in whom you used Prolift to treat pelvic organ prolapse during the course of your career?
A. I want to say maybe 25 or 30.
Q. Okay.
A. You know, that ballpark.
Q. Were you trained on any type of non-mesh

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surgery to treat pelvic organ prolapse?
A. Yes.
Q. What procedures did you use?
A. So, you know, in my residency training from 1980 to 1984, a lot of the gynecologic surgery that we did was for the treatment of different aspects of pelvic organ Prolift [sic], so --
Q. I have given it to you now. You mean prolapse?
A. -- we did -- we did anterior colporrhaphies, we did posterior colporrhaphies, we did colpocleisis, we did abdominal sacral colpo-suspensions. We did some sacrospinous suspensions. I might be leaving something out, too.
Q. Was 2005 the first time that you used mesh to treat pelvic organ prolapse?
A. No.
Q. What other mesh products did you use?
A. So, you know, for a number of years prior to that, we were using mesh abdominally to do -- to treat pelvic organ prolapse. We were doing abdominal sacral colpo-suspensions using different kinds of mesh products.
Q. Would you have been using kits for that

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procedure or did you use a piece of mesh that you cut to the right size?
A. We used a piece of mesh that we then custom-tailored and cut to fit the patient.
Q. Other than Ethicon's Prolift kit, did you use any other mesh kits for pelvic organ prolapse?
A. I believe, for a short time prior to that, we used another product, but primarily, you know, our group, you know -- after doing a review of the different products on the market, our group decided to use the Prolift.
We thought that that was, you know, the -- one of the best products on the market. So as a group, we reviewed the information and picked that one to use.
Q. Did you continue using Prolift throughout your career? After you had started, obviously.
A. We -- we ended up stopping using it. I don't recall exactly when, but there was a point that we -- we ended up not using it anymore and we did other surgeries instead.
Q. Do you recall why that was?
A. There were a number of reasons. The -- the main -- One of the main reasons for using Prolift was that it gave us an option that was much

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more patient-friendly. Prior to using Prolift, we would make a big incision in the abdomen and patients would have this really big surgery and have a long hospital stay, and there was morbidity and complications. And a lot of our patients were older and -- and some of them, you know, just barely squeaked by.
Prolift was a much smaller -- The Prolift surgeries, they were done in combination with vaginal surgeries that we had done for years and years. They were much more patient-friendly. They had much less pain, much less morbidity, much shorter hospital stays, and they -- they promised, you know, to give the same long-lasting results.
And after we had several years' experience with Prolift, we -- we -- you know, after seeing our own patients, we saw that the results overall were pretty good, but they weren't quite as good as we hoped. And, you know, every surgery has complications, and the complication rate with Prolift was maybe a little bit higher.
And then, at that time we learned how to do laparoscopic, you know, sacral colpo-suspensions, and we felt that laparoscopic sacral colpo-suspensions were a better way to go.

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They had the -- the short hospital stay, low morbidity, and we felt they had better -- better results long term and...[pause].
Q. At what point did you start doing the laparoscopic procedures?
A. You know, it's been a while. Could have been, I don't know, 2008, 2007, or 2009, somewhere in there.
Q. Okay. Did you attend any Ethicon professional education events?
A. I did.
Q. Okay. Do you remember when?
A. Well, before we started using the Prolift, we went to an Ethicon surgical training conference, and I believe it was in Wisconsin, in Milwaukee or some city there. I remember flying in with my partner, Audrey, and we had a weekend conference where we, you know, actually sat in and watched surgery being done and...[pause].
Q. Was that just one Ethicon event that you attended?
A. One Ethicon training program regarding Prolift. I went to others involving TVT-Os and TVTs and --
Q. Understood. Did you find the Ethicon

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professional education event regarding Prolift helpful?
A. Very helpful. It was done very well.
Q. Do you recall receiving any materials at that event?
A. I believe we received a little certificate saying that we completed the training. There were some materials, I think, regarding the product, you know. I don't recall exactly. It's been a -- quite a while.
Q. Sure. Do you agree that Ethicon's professional education event provided you with information on how to perform a procedure, but it didn't teach you how to be a pelvic floor surgeon?
A. I would agree with that. I think we were all pelvic floor surgeons, and -- and this -- this gave us additional information. It was a helpful adjunct to what we were doing.
Q. I'm going to talk to you about some of your medical records related to Ms. Smith.
Before I do that, though, I'm going to mark as Exhibit 2 a copy of the notice of deposition in this case.
(Zenthoefer Exhibit 2 was marked for identification by the Reporter and is annexed

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hereto.)
BY MS. MERK:
Q. I just placed it right here. I can't reach you over there.
A. What am I supposed -- what am I supposed to do with this?
Q. Have you seen this document before?
A. I think so, yes.
Q. If you turn to the third page, it's entitled Schedule A. You are there. It's double-sided.
A. Oh, here. Okay.
Q. And it identifies a number of documents that I had asked you to search for and bring with you today. Did you find any documents that were responsive to these requests?
A. No. I -- I retired, and I -- I don't have, you know, things like this anymore.
Q. Okay. Did you bring any documents with you today?
A. I did -- I did not.
Q. Okay.
A. Just what you sent me.
MS. MERK: Now I am marking as Exhibit 3 some medical records.

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(Zenthoefer Exhibit 3 was marked for identification by the Reporter and is annexed hereto.)
BY MS. MERK:
Q. And I'm going to ask you some questions about these. And these are some of the records that we received from plaintiffs' counsel in this litigation.
We have not received the full records yet from Kaiser Permanente. I understand that they are a little behind on their records production. But we do have some of your records, and those are the ones I'm going to ask you about.
A. Okay.
Q. And are these the records that we provided to you before the deposition?
A. Well, without going through every single page, it appears to be about -- appears to be the same thing.
Q. Okay. The first page of Exhibit 3, which is Bates stamped 145 at the bottom, is a record from a visit dated January 30th, 2006. Do you see that?
A. I do.
Q. Okay. And Mrs. Smith was 64 years old at

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the time; correct?
A. Yes.
Q. What was the reason for her visit?
A. In her own words, she said: "It feels like my insides are falling out."
And she had additional complaints other than that. She had some complaints of mild stress urinary incontinence.
Q. Did you conduct a physical exam on this date?
A. Yes. She was also complaining of difficulty starting her urine stream. She would have to change position, sometimes lean to the left or the right in order to get her stream to start and empty her bladder.
She also had difficulty eliminating or passing bowel movements. She had to insert her fingers either inside the vagina or push on the perineal body and -- and help express stool.
She was also incontinent of flatus.
Q. Did you perform a physical exam that day?
A. I did.
Q. What were your findings on physical exam?
A. The first thing I noticed was that the perineal body was somewhat attenuated. It looked

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like it had been damaged in childbirth. And her largest baby was nine pounds. It was a forceps delivery. And forceps deliveries often cause damage to the pelvic floor. So it wasn't surprising.
She had a large cystocele. So the upper vaginal wall and the bladder were falling down.
She also had a moderately large rectocele.
I thought the vaginal cuff was fairly well supported, but I was examining her lying down, so that could always be different standing up.
She had had a hysterectomy, so she didn't have a cervix and uterus and -- and ovaries anymore.
And we did a uroflow, and she had a fairly normal flow. Her post-voids residuals were okay.
We did systematic testing, so we were testing to see how well the nerves in her bladder were working, how well she, you know, sensed feelings. And that all seemed pretty normal for sensation. When she first felt some water in her bladder was about 50 milliliters, second sensation 150, and then she was -- felt very full at 400. So this was all pretty normal.
And then we had her cough. So her bladder

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was dropping down. When that happens, the urethra kinks and patients don't leak much urine. So we actually pushed the bladder up and had her cough, and we were able to demonstrate some urine leakage with coughing. And that's stress urinary incontinence.
Did cystoscopy, and things looked pretty normal in the bladder.
Did urethroscopy, and the urethra seemed to close nicely, so it was functioning pretty well.
And that was most of the exam.
Q. Okay. You had noted that she'd had a hysterectomy in the past.
A. Yes.
Q. And on the first page of that record which is 145 at the bottom, it states:
"The OB-GYN encountered severe adhesive disease."
What does that mean?
A. And she was -- I quoted the patient. She said that her doctor described it as her abdomen being filled with a bucket of glue.
So adhesions are scar tissue, and severe adhesive disease is when everything is scarred together, when there is dense scar tissue between

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loops of bowel, between bowel and bladder, you know, small bowel and rectum and -- and the -- and the ureters and the peritoneal lining.
And what's also interesting is that she says that her hysterectomy surgery, when it was done, was -- took seven hours. This is an incredibly long time. Normally a hysterectomy should be, you know, one and a half, two, two and a half hours. Seven hours is just extraordinarily long.
And -- and that, I think, is an indication that -- that this -- she had some -- that what was said earlier, that she had severe adhesive disease, was actually true.
Q. And how, if at all, did this history enter into your treatment of Mrs. Smith?
A. So I think when you hear this, when you get this kind of information in the history, it sends the message or it tells you that you should not do surgery in this patient's abdomen, that it is incredibly risky, and only in a life-threatening, life-and-death situation should you enter that -- that person's abdomen.
So for the kind of surgery that we do, even though pelvic relaxation and the problems

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associated with that, even -- even though that is very distressing and upsetting for the patient, it's not a life-and-death situation. And so -- so the conclusion -- I think my conclusion was that in no way would I want to make an incision in her abdomen.

So continuing on, she was the ideal candidate for a vaginal repair and she was an ideal candidate for a Prolift.

Q. Did you discuss Prolift as a possible option with her during this first visit?

A. Probably not very much. Generally, at the first visit, I try to avoid talking about surgery. I try to talk about nonsurgical treatments.

Q. What nonsurgical treatments were available to her?

A. Well, I think -- I think one of the most important treatments is physical therapy. And so under -- my plan, you know, was -- was physical therapy referral.

The tissues in the pelvic floor and the vaginal area, they become stronger, they improve in their functional ability with estrogen hormone cream. So I recommended that.

And -- and sometimes incontinence issues,

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you know, have some -- some -- some dietary kind of provocative factors. So I recommended some diet modification, usually cutting out caffeine and soda pop, things like that.

Q. At the time that she came to see you, had she already failed with a pessary?

A. You know, I was going to say that. Ordinarily we would recommend pessaries. That would probably be the mainstay, the sort of the main way, nonsurgically, that we treat prolapse.

And she had seen Dr. Miksovsky, another obstetrician-gynecologist, and my notes say that he treated her with two pessaries, and both were unacceptable to the patient.

The first one was painful, and the second one caused bleeding, so the patient stopped using the pessary. And I don't think she was willing to try a pessary again. Otherwise we would have done that.

Q. When she came to see you in January of 2006, in what way was pelvic organ prolapse affecting her life?

A. Well, her own words were that she felt like her insides were falling out. She couldn't pee normally. She couldn't eliminate stools

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normally. She was incontinent of flatus and urine.

I think it was affecting her life quite a bit. She was -- She had seen Dr. Miksovsky, you know, at least a couple of times before that.

Q. Move forward to the page ending in 153 at the bottom. This is a record from a visit on April 6, 2006.

A. Okay.

Q. Okay. And under Reason for Visit, it says counseling. Do you see that?

A. Yes.

Q. Okay. Can you describe for me what that means, a counseling visit?

A. Well, in -- March 14th, on the previous page, the patient called my office and spoke to Claudia Peterson, our nurse, and it says that she was referred for conservative therapy, but she would like to have surgery, and she wanted to have an appointment with me to discuss surgery. She did not want to do physical therapy.

Our nurse, Claudia, was a really strong proponent of conservative surgery, physical therapy, using pessaries. So I'm -- It was her normal routine to really encourage patients, you know, and really, really encourage them to -- to

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give conservative, you know, measures a good try.

So after talking to the -- Mrs. Smith on the phone, she didn't want to pursue that anymore. Instead she wanted to come see me. So the appointment was made on the 6th of April to talk about surgery. She was done with conservative therapy.

Q. And what did you discuss with her as it relates to Prolift?

A. So we discussed doing an anterior and a posterior colporrhaphy with Prolift. We discussed doing a mid-urethral sling. And it was our preference to do a TVT type of sling, but, because a TVT sling actually enters the abdominal cavity and she had the history of severe adhesions, we decided to do the transobturator sling, which avoids going into the abdomen.

Q. Did you consider using native tissue?

A. You know, my understanding is that native tissues, you know, did not -- were not helpful and did not -- were not associated with improved results, and so I don't think we discussed that.

We -- I think we discussed doing -- so we -- I think we discussed doing a native tissue repair, just an anteroposterior repair, but I

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guess -- I guess what I should have said is we -- we didn't discuss using other tissues, like from -- from animal sources, you know, collagen from animal sources and things like that.

Q. What was it about the Prolift product that made you decide to recommend it to her?

A. I think the reason that I recommended Prolift is that it gave -- it was associated with better long-term results. You know, I had been doing anteroposterior repairs since my residency program in the 1980s, and -- and they just have a very high failure rate.

When you use the patient's own tissues, which we call a native tissue repair, they just have very high failure rates. And using mesh is associated with better long-term results.

Q. Was Prolift a reasonable and appropriate option for Ms. Smith?

A. Yes, it was.

Q. And in your hands, did Prolift work to treat your patients with prolapse?

A. Yes, it did.

Q. On Page -- the following page of your packet there, it ends in 820 at the bottom, this is the informed consent that Ms. Smith signed on

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April 12th, 2006. It says in the middle "PARQ discussion held"?

A. Right.

Q. What is that?

A. So this -- this is a form -- This page was not included in the information that was sent me. So I'm really glad you found this.

Q. Okay.

A. This is the informed consent form. And "PARQ" stands for "procedure alternatives risk questions" discussed.

Q. What risks did you discuss with her?

A. Well, you know, I spent a lot of time talking about risks to patients because I think surgery is a big deal. So, you know, you start out with the obvious ones. You know, there is a small chance could you die.

There could be major morbidity. You know, you could have a heart attack, you could have a stroke, you could have blood clots.

There could be infections. The surgery can fail. There is no guarantee that a surgery for -- to correct pelvic organ prolapse, there is no guarantee that it will work, either in the short term or in the long term.

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You know, medical complications, you know, from a -- drug reactions, allergic reactions, infections, whether they be where we do the surgery or in other parts of the body like -- like lungs, bladder, kidneys.

And then, you know, there's all the risks and complications of a surgery where we don't use mesh.

And then, when we do use mesh, there is a whole 'nother discussion that that then -- that we go into. And the most common, I think, complication with mesh is vaginal mesh erosion. That's probably the most common one.

Q. How would you -- I'm sorry.

A. Sure.

Q. How would you have explained vaginal mesh erosion to her?

A. Basically, the mesh sort of coming through the vaginal skin, coming out the vagina.

Q. Did you discuss any complications associated with vaginal mesh erosion with her?

A. Yes, I'm sure I did.

Q. And what would those have included?

A. So when mesh -- so -- And I also mention that mesh can also internally erode into other

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structures, you know, other organs and things.

But specifically vaginal mesh erosion, the most common things that patients would notice would be vaginal bleeding, vaginal spotting, vaginal discharge. If they are sexually active, their partner -- The most common person that notices it is actually their partner because, during vaginal intercourse, they feel -- the male partner feels the mesh and it feels like sandpaper, and they have discomfort. They get poked. And so those are things I discussed with everybody.

I also discussed, you know, the possibility of having a second surgery to deal with mesh erosion. And, you know, if it's -- and then, you know, the mesh can also erode into the rectum, it can erode into other abdominal organs. And so it was -- it was all discussed.

Q. Did you discuss with her the possibility of pain associated with mesh erosion?

A. You know, any -- any kind of pelvic surgery is -- can be associated with pain, and -- and so that -- that was also discussed.

Q. Did you discuss a risk of other urinary symptoms that could result after the surgery? Urinary dysfunction, for instance?

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A. You know, when we talk about doing slings under the bladder, you know, I had a spiel, sort of a standard discussion in which I told patients that tensioning the sling was very tricky, was very critical. If we didn't tension the sling tight enough, you know, their stress urinary incontinence, their urine leakage problem wouldn't be better or wouldn't be improved enough that they would be happy. And if we made it too tight, then they would have trouble emptying their bladder. So, you know, we had that discussion too.

Q. Anything else that you would have discussed related to the risks? I just wanted to make sure you had a chance to finish your answer before I move on to something else. I know I interrupted you a couple times.

A. So dyspareunia, pelvic pain, different kinds of morbidity, need for further surgeries down the road, nerve injuries, bowel injuries, bladder, rectal injuries. That pretty much, I think, covers it.

Q. Approximately how long would it take you to have that risk discussion with your patients?

A. So I had 30 minutes for the pre-op appointment, and I generally always went over. I

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generally always took 45 minutes.

And most of that time was going over the consent form because, by the time they come to the pre-op visit, you know, we have already established a surgical plan.

In a few cases the patient might say, "Well, I want this additional thing done," or, "I don't want this done," or, "I want it done differently." But most of the time, when the patients came to the pre-op visit, the plan was established, accepted.

The physical exam was pretty brief. You know, heart, lungs, are you healthy, are you coughing, are you sick, are you well. And most of the discussion was all about the surgery, the risks, the alternatives, and answering questions.

Q. After having that discussion, did Ms. Smith elect to go -- proceed with the procedure?

A. She did.

Q. I'm going to ask you to turn to your operative report, which starts at Page 681, a few pages back from you are. I'm sorry the pages aren't in numerical order at the bottom. We try to keep them in chronological order.

A. 681. Is that a page number or is that --

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Q. At the bottom here [indicating].

A. Okay.

Q. Okay. And does this look to be the operative report following Ms. Smith's implant procedure?

A. It does.

Q. Okay. And the date of her procedure was April 17, 2006; right?

A. It was.

Q. Were there any complications during this procedure?

A. I don't recall any complications.

Q. Did the procedure essentially go as planned?

A. It went very well. I did it with my partner, Audrey Curtis, who was a very skilled surgeon, and we worked very well together and...[pause].

Q. One record that we have not yet found were your discharge instructions. What were your standard discharge instructions following a Prolift procedure?

A. Well, there were -- The most obvious ones were restrictions in lifting. So, you know, usually I told patients, you know, not to lift

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like -- like more than 10 pounds for the first couple of weeks and no more than 15 pounds for the next month after that.

We told patients they should not put anything in the vagina. So, you know, no vaginal intercourse, no douching, no vaginal estrogens with applicators.

We had discussions about urinary retention, voiding problems, bladder infections. Those were all common issues after surgery.

And -- and encouraged the patient again and again and again to call my office if there was anything out of the ordinary or if they had any concerns or questions.

Q. I want to move on to your post-operative care of her. If you'd turn to the next page, which has a stamp of 163 at the bottom, the date of this visit was April 25th, 2006, so eight days after her procedure.

How was she doing at this time?

A. So I always liked to see my patients one week after surgery, especially the ones that I did put slings under the urethra, because if the sling was too tight, at this time, one week after surgery, we were still within that small window of

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time where we could go back to the OR and loosen it and have good results.

So she came and saw me one week after the surgery. And my note says -- and I don't -- my note says that when she was discharged from the hospital, she had a little right leg pain, but this was now completely resolved. She was voiding normally. She no longer had stress urinary incontinence. She was taking tub baths. And she had no concerns at all.

And then I examined the incisions, and they were all healing well. I inserted a very small speculum into the vagina and very gently, carefully examined her, and all the incisions inside were healing.

Could not see any mesh and -- and I thought she was doing very well. And then, when -- I encouraged her to start using estrogen cream when she was more comfortable.

Q. The next time that you saw her was just over a month later, on May 31st of 2006, and that's on Page 165. I think --

A. Oh, April 25th and now 31 May. Okay.

Q. Okay. And how was she doing at this post-op visit?

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A. My notes say that she was doing very well, patient is very pleased, she no longer splints bowel movements.

So one of her main problems was she was having a lot of difficulty with bowel movements. She would have to insert her fingers and push on the lower vaginal wall and try to get that stool to come out, and she -- and that -- and she wasn't doing that at all anymore.

And she has -- she had no stress urinary incontinence. So that was another one of her complaints. She had no urgency symptoms. And we always asked about urgency because urgency symptoms sometimes, you know, could be a sign that the sling is too tight under the urethra. And so she had none of that.

She was complaining of her urine being a little cloudy and a little bit of burning, and she wondered if she had a bladder infection.

Q. Did you start her on Premarin cream at this time?

A. My notes say that I did.

Q. Why did you do that?

A. That was our routine. The tissues in the pelvic floor in the vaginal area, they are

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different than tissues elsewhere in the human body. They are estrogen-dependent. They need estrogen to be healthy, to be strong. And without estrogen, especially when somebody is 65, they atrophy, they become thin, they become weak, and then the incidence and the likelihood and the probability of mesh erosion increases quite a bit.

So pretty much for -- for all of our patients who had pelvic floor reconstruction surgery, we recommended, you know, vaginal estrogen for everybody. We felt that the local effects were -- were very important.

The amount of systemic absorption was small, and -- and unlike oral estrogen, which has other risks, we felt that this was very, very safe.

Q. Do you want to go off the record now a second?

A. Pardon?

Q. Do you need to go off the record for a second?

A. I'm all right. I'm just going to put a cough drop in.

Q. Sure. You also noted during this visit that there was a small stitch visible at the vaginal cuff apex. Do you see that under A?

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A. I do.

Q. What did that mean?

A. Well, the stitches that we used were absorbable, but they took, you know, two months, three months, four months, you know, longer -- There are different kinds of absorbable sutures. Some are reabsorbed more quickly than others. So this was normal.

Q. Okay.

A. Excuse me.

Q. Sure. You saw her again in April of two -- I'm sorry, in August of 2006. And that is at Page 175. Do you see that?

A. So April 15th?

Q. It's August 15th.

A. Or August 15th.

Q. It was my fault. I said it first.

A. Okay. I see it.

Q. Was she still doing well at this time?

A. So it looks like August 15th was a -- was a nurse visit.

Q. Okay.

A. And I actually saw her August 23rd.

Q. And that's at Page 177?

A. Yes.

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Q. Okay. How was she doing on August 23rd?
A. So on August 23rd, my note says she was very pleased with the results of the surgery. She states that the problems she had with bowel movements before the surgery, that is, splinting, having to put her fingers in and provide -- and push and help evacuate stools, was completely resolved.
So sometimes when we do the surgery, sometimes patients still have to splint, but not as often, and sometimes the success is partial. In her case, it was completely resolved. So she was very happy about that.
Q. Moving to -- I'm going to skip a couple of appointments just for the sake of time. Moving to the page that's 198 at the bottom, and the date of the visit is July 18, 2007.
A. Okay. I found it.
Q. How was Mrs. Smith doing at this time?
A. So, you know, I don't have any independent recollection, so I will just read my note.
Q. Uh-huh.
A. It says that she doesn't have any urinary incontinence during the day now. So during the daytime, when patients are active, when they are

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lifting, when they are walking, when they are going up and down stairs, that's when they usually leak. When patients are lying down at night, sleeping, that is a time when they are much less likely to leak.
So she was telling me that -- that she had no -- she had no incontinence during the day, but she has a little leakage at night. So that's a little -- I wasn't quite sure what to think about that. Her pad was a little wet. She had to get up three times at night. That's pretty common when -- you know, when people are in their sixties.
She says she is able to walk to the bathroom okay at night without leaking, but she -- when she arises from the supine position, she leaks a little bit. So when people stand up, they have to strain a little bit. So that's not too unusual.
Then my note says she complains of frequent urinary tract infections, that she feels like she always has a urinary tract infection. The last one was in December. So this note was in July, and the last one was in December. She frequently takes cranberry juice when she feels she has symptoms.
And she had a urethral discharge that was

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slightly green in color. She said she was using estrogen cream. Rarely sexually active. She had told me her husband was pretty ill. She stated that the surgery had helped her 90 percent, and she no longer -- she was happy she no longer leaked urine with activities in the daytime.
Q. Was the Prolift still successful in treating her prolapse?
A. And then she also said that she had a little bloody discharge from the urethra. And then on my examination -- So I did measurements on this -- on this day.
And the bladder -- it looks like the bladder was fairly well supported. The posterior vaginal wall was fairly well supported. So yes, things -- it looked like the surgery was -- was -- was still successful.
Q. I'm going to move ahead to 2011, April 5th of 2011, and the page number at the bottom is 388. At this time did she report to you that she had no complaints or problems except the high cost of the vag E cream?
A. ROS is Review of Symptoms, and I wrote down that she has some urgency symptoms like when she had a urinary tract infection in the past. So

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I think that was her only concern that day.
Q. Can we move ahead to the page that's labelled 390. It says, about a third of the way down:
"Spent 25 minutes with patient today. More than 50 percent of visit was face-to-face counseling, discussing mesh erosion, vaginal atrophy, and urgency symptoms."
Why did you have that discussion with her on that date?
A. Well, I did an examination. So on Page 389, when I examined her, at the -- towards the bottom of the page, where it says cuff, that's the very top of the vagina, I wrote:
"At the apex there is about a 1 centimeter area of mesh that was exposed. No abnormal induration or purulent discharge."
So no sign of infection. And I did a rectal exam, and I did not find any mesh inside the rectum. So we had a long discussion about the mesh in the vagina.
And -- and the other thing I noticed when I examined her is that her tissues were very

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atrophic, they were very thin, very fragile, very weak.
Q. Was that one of the things that you referred to earlier could lead to a mesh erosion, when the tissue has become thin and weak?
A. Right. And we spent a lot of time talking about the importance of using vaginal estrogen.
Q. Moving forward to the page labeled 401, the date of the visit was June 24th, 2011. Are you there?
A. Uh-huh.
Q. Okay. What was her chief complaint during this visit?
A. So I saw her in January, and that's when we first noticed a little bit of mesh erosion. So sometimes when patients -- sometimes that will heal over, the vaginal skin will grow over the mesh and you get reepithelialization.
So in June, when I saw her, this was an appointment that was scheduled to see if things had -- had healed, if reepithelialization had occurred, you know, with using the estrogen cream. That was the purpose of this visit. It does not appear that she had any complaints.
Q. Was she experiencing any pain associated

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with that mesh erosion?
A. It's not mentioned here in my note.
Q. Would you have mentioned that?
A. I would have if she would have told me.
Q. Okay.
A. Generally, mesh erosion is not associated with pain. And -- and the patient themselves is generally unaware of that. They may notice a little bit of funny vaginal discharge.
More typically, their partner notices it during intercourse. Their partner has pain. Not the patient, but their partner. And she was not sexually active.
Q. If we move forward to the page marked 414, did you recommend removing that part of the mesh that was eroded?
A. So that had been the plan that was made in January, that we do conservative therapy using the vaginal estrogen cream, and we did that for about six months.
And then, if it doesn't heal, then we do surgery and remove the mesh and then sew the vaginal skin edges together and give it a chance to heal. So yes.
Q. Okay. Move forward a few more pages to the

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page marked 549.
A. 549.
Q. Yes.
A. 549?
Q. Yes.
A. Because the last one I have is 453.
Q. Yeah. They're out of order. It's just a couple pages past where we were.
A. Oh, here it is. Okay.
Q. Okay. This, I believe, is the operative report for the procedure to remove that piece of exposed mesh -- or not the full report, but a note concerning it. I'm sorry. I don't believe that we have actually obtained the record of the operative report.
A. So it was my custom to dictate an op note even on little procedures that I did in the outpatient surgery area. So this says H & P Update. So this was something we had to do right before we did the surgery. So I don't -- I don't see any other summary dictation here.
Q. Okay. We may have not obtained it yet.
A. Right.
Q. Would you have discussed any risks of this surgery with her?

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A. Oh, yes.
Q. And what were those risks?
A. Well, you know, this -- this was a much shorter surgery, but -- but, you know, still -- still there are associated risks.
The location of the mesh exposure is very close to the bladder, very close to the rectum, very close to pelvic nerves, very close to ureters. So all of those things could be -- could be injured. Doesn't happen often, but could be.
I always did a cystoscopy, that is, putting a scope in the bladder, making sure that things were functioning, making sure that the ureters were making urine, making sure there were no injuries to the bladder. So that was done at this time.
Patients are always told that there's no guarantee that -- that -- that this is going to heal okay. You know, I think I told patients there was maybe an 80 percent chance that this would heal and there was maybe a 20 percent chance that they would have a mesh erosion down the road again.
I always emphasized the importance of using estrogen in the vagina.
And then I think at one of the later

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notes, when I was reviewing the chart, I read that the patient wasn't actually putting estrogen in the vagina. She was just putting it on the outside. So even though my note says she was using estrogen daily, later on, in retrospect, I figured out that she really wasn't using it at all up at the top of the vagina, she was just using it on the outside.

Which didn't really help where the mesh was exposed.

Q. So can that -- I'll call it a failure -- can that failure to use the estrogen in the way that you had recommended have contributed to the mesh erosion?

A. Absolutely.

Q. Understanding that we don't have the operative report, I'm going to move to the next visit after you had removed that portion of the mesh.

So the page I am on is 437, and it's actually the back of one of the pages. Okay. How was she doing following the removal of that portion of the mesh?

A. So on this visit -- This visit is with my nurse, Carleen Pompeii. And she says that she came in for a voiding trial. So I don't have the -- all

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the chart information, but it sounds like they filled -- that my nurse put 275 cc's of sterile water in her bladder with a Foley catheter.

So it sounds like she maybe went home with a Foley catheter from the surgery, like she couldn't pee, and now she is in the office to see if -- if -- if -- with resolution of the swelling, with healing, if she can now pee.

And my nurse discovered that she voided normally. So the catheter was removed and she went home that day.

Q. Okay.

A. And my nurse doesn't write that the patient was having any problems or concerns. If the patient would have said something, she would have -- she would have called me.

Because, you know, either -- either I was in the office that day, too, or one of my partners. So when she sees patients for a voiding trial, if they have any concerns at all, they always get a doc or urogynecologist, then have the doc examine the patient, talk to the patient.

So the way I interpret this is that she was doing fine, didn't have any problems, she peed okay and went home.

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MS. MERK: I want to go off the record for a few minutes, please.

THE VIDEOGRAPHER: The time is now 10:25. Going off the record.

(Recess taken.)

THE VIDEOGRAPHER: Time is now 10:35, and we are back on the record.

BY MS. MERK:

Q. Doctor, do you agree with me that no surgery is a hundred percent risk-free?

A. Absolutely.

Q. And is it fair to say that you familiarized yourself with the safety information about mesh before using it for the first time?

A. I think so.

Q. How were the ways that you educated yourself? We have already discussed the Ethicon professional education event. What are the other ways that you educated yourself about mesh?

A. Well, you know, I was a member of professional societies, like AUGS and IUGA. I read their publications regularly. I attended continuing education conferences regularly.

Q. Did you also have discussions with your colleagues at Kaiser?

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A. Frequently.

Q. Do you agree that all pelvic floor surgeries have basic known risks?

A. Again, yes.

Q. Does a bad outcome mean that there was something wrong with the surgery?

A. No.

Q. Does a bad outcome mean that there was necessarily something wrong with the product?

A. No.

Q. With regard to Prolift, if Ms. Smith did, in fact, experience erosion, does that mean that there was something wrong either with the surgery or with the product?

MR. CANTRELL: Object to the form.

You can answer the question. I'm just objecting for the record.

THE WITNESS: No. I think -- And again, I just want to add that I think her noncompliance, her failure to use estrogen inside and at the top of the vagina, at the vaginal apex, a common area of mesh erosion, I think was a contributing factor.

BY MS. MERK:

Q. In your hands, did you find that the benefits of Prolift for your patients outweighed

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the risks of Prolift?
MR. CANTRELL: Object to the form.
THE WITNESS: I think so.
BY MS. MERK:
Q. And was that true during the entire time that you used Prolift in your patients?
A. Yes.
Q. Did you find that Prolift was a safe and effective treatment in your patients?
A. Right. With -- Again, you know, no surgery is guaranteed safe, but yes.
Q. That was something that you knew before you implanted the first Prolift product into one of your patients; correct?
A. Yes.
Q. Do you generally provide patient brochures to your patients?
A. We had some brochures in our clinic that all the urogynecologists used that talked in general terms about pelvic organ prolapse and treatment for that. So --
Q. Some doctors that we have spoken to used it to go through risks with their patients and others just left it out in the waiting room for their patients to pick up.

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How did you use brochures, if at all?
A. Well, you know, I -- I -- it was my custom, my practice to draw pictures and to show -- because I think a picture just conveys ideas and information much better than just talking. So I always drew pictures out, and I sent those home with patients.
And I showed them, you know, where their bladder, vagina, rectum was, where the mesh would be and...[pause].
Q. I am going to -- Well, first I'm going to ask you. Do you have an independent recollection or do any of the records that we have reviewed today indicate that you gave a brochure to Mrs. Smith?
A. There is nothing mentioned here. So I -- I don't have an independent recollection.
MS. MERK: I'm going to mark as Exhibit 4 a brochure for Prolift.
(Zenthoefer Exhibit 4 was marked for identification by the Reporter and is annexed hereto.)
MR. CANTRELL: Well, if you're going to ask him questions about this, I'm going to object for the record, because this is a 2008 version. So it

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wasn't the version that was even applicable at the time she had her surgery.
MS. MERK: Okay.
Q. Can you turn to the page that's 292 at the bottom. All right?
A. All right.
Q. There is a statement of risks associated with Prolift here, and it states:
"All surgical procedures present some risks. Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of mesh material becoming exposed. Exposure may require treatment. For a complete description of these risks, please see the attached product information. Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and

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understand the benefits and risks of mesh implant surgery before deciding to treat the condition."
Do recall ever reading that paragraph?
A. I don't recall seeing this brochure.
Q. Okay. Were you aware -- Prior to the time that you implanted Prolift in Ms. Smith in 2006, were you aware of each of the risks that are stated here?
A. Yes.
Q. Prior to implanting Prolift in Mrs. Smith in 2006, were you aware that some of the complications associated with pelvic surgery involving mesh included injury to blood vessels of the pelvis?
A. Yes.
Q. And of difficulty urinating?
A. Yes.
Q. And pain?
A. Yes.
Q. Scarring?
A. Yes.
Q. Pain with intercourse?
A. Yes.
Q. Bladder and bowel injury?

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A. Yes.
Q. And are these all risks that you discussed with Mrs. Smith?
A. Yes, they are.
Q. You can put that one aside.
I have marked as Exhibit 5 a statement from the FDA, and it is issued October 20th, 2008.
(Zenthoefer Exhibit 5 was marked for identification by the Reporter and is annexed hereto.)
BY MS. MERK:
Q. And my question for you is if you have ever seen this document before.
A. I believe I have.
Q. After you received this document, did you continue to use Prolift in your patients?
A. I believe we did.
Q. You can put that document aside.
A. My partners and I, you know, we -- we regularly had -- you know, with our nurses, we had urogynecology meetings, and I can recall seeing this and discussing this.
But it wasn't too long after this that we started doing more laparoscopic, you know, surgeries and less Prolifts. This was sort of when

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directions seemed to change.
Q. The laparoscopic surgery, was that a new procedure that you had not done before?
A. So the procedure we had done before by making a big incision in the patient. And then we would take mesh and -- and attach it to the vagina, on the anterior wall and the posterior wall, we made a Y shaped graft, and then we would attach it to the anterior ligament of the sacrum.
So what was different was that this very long, difficult surgery that required a big incision, we were now doing it laparoscopically through little incisions.
And -- and -- and, you know, in the beginning, I didn't think we could ever do it, you know, but -- but then, you know, with this trick and that trick and this technique and this change in technique, you know, eventually we were able to do it. But they were just incredibly long surgeries. I mean, the first one we did, I don't know, six, seven hours?
And then, you know -- you know, we were on the bottom of the learning curve, and then we got better. And then -- so anyway...[pause].
MS. MERK: I have next marked as Exhibit 6

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a chart that we have prepared, and I'm going to ask you some questions about it.
(Zenthoefer Exhibit 6 was marked for identification by the Reporter and is annexed hereto.)
BY MS. MERK:
Q. This chart lists some of the potential risks of non-mesh pelvic organ prolapse surgery. I'm going to go through them each and ask if you were aware of these as risks of non-mesh surgery.
Acute and/or chronic pain with intercourse. Was that a risk that you were aware --
A. Yes.
Q. -- of with non-mesh surgery?
Acute and/or chronic pain?
A. Yes.
Q. Vaginal scarring?
A. Yes.
Q. Infection?
A. Yes.
Q. Urinary problems?
A. Yes.
Q. Organ and nerve damage?
A. Yes.
Q. Bleeding?

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A. Yes.
Q. Wound complications?
A. Yes.
Q. Inflammation?
A. Yes.
Q. Fistula formation?
A. Yes.
Q. Neuromuscular problems?
A. Yes.
Q. Repeated surgeries to treat an adverse event?
A. Yes.
Q. Recurrence or failure?
A. Yes.
Q. Foreign body response?
A. (No response.)
Q. For non-mesh --
A. Yes.
Q. -- surgery, so including --
A. Yes.
Q. -- other products that -- Okay.
Erosion or exposure of extrusion -- or extrusion, excuse me, of sutures or grafts?
A. Yes.
Q. Contraction or shrinkage of tissues?

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A. Yes.
Q. And were you aware of all of these potential risks of non-mesh surgery before you implanted Prolift in Mrs. Smith?
A. Yes.
Q. Were you aware that if one of these complications resulted from a non-mesh surgery, that the complication could be temporary or it could be chronic in nature?
A. Yes.
Q. And were you aware that some of these risks, the complications could be mild, moderate, or severe?
A. Yes.
Q. On the back we have added a list of potential surgeries with mesh and non-mesh surgeries. Were you aware that all of the risks listed under the mesh column could be potential risks associated with mesh repair for pelvic organ prolapse?
A. Yes.
Q. And were you aware of all of these risks before you implanted Prolift in Mrs. Smith?
A. Yes.
Q. Were you aware, with respect to mesh

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procedures, that each of these potential risks could be chronic or they could be temporary?
A. Yes.
Q. And were you aware that they could be mild, moderate, or severe?
A. Yes.
Q. And is that information that you took into account when doing your risk-benefit analysis with respect to Mrs. Smith?
A. Yes.
Q. Doctor, have you seen any record or do you have any independent knowledge of whether Ms. Smith experienced a foreign body reaction?
A. (No response.)
Q. Let me restate the question.
After implanting Mrs. Smith with Prolift, did you find any evidence that she had been harmed by a foreign body reaction?
A. No. The mesh expose -- the mesh exposure at the top of the vagina seemed to be pretty asymptomatic. I am the one that noticed it on a routine exam.
Q. Have you seen any evidence that Mrs. Smith experienced any cytotoxicity?
A. No.

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Q. And that, can we agree, means cell death?
A. Well, that's --
Q. Simply stated.
A. -- what the term means.
Q. Right. Did you see anything in the record to indicate that Mrs. Smith's mesh had degraded in any way?
A. No.
Q. Or that she had roping or curling of the mesh?
A. No.
Q. Was there any evidence of infection with the mesh?
A. No. And my note specifically said that there was no purulent drainage, so no pus. And no induration. So none of the hallmark signs of infection.
MS. MERK: Okay. I'm going to reserve the rest of my time for rebuttal.

- - -

EXAMINATION

- - -

BY MR. CANTRELL:
Q. Doctor, I have a few questions for you. I probably won't be quite as long. I'll try not to

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repeat a question, but if I do, forgive me.
Now, you understand that Ms. Smith is not making any allegations that you did anything improper or negligent in any way in your treatment of her. Is that correct?
A. I understand that, yes.
Q. Okay. And I believe you stated earlier in your deposition testimony that pelvic organ prolapse is a functional disorder and not a life-threatening disease. Is that correct?
A. In the vast majority of cases, it's very distressing to the patient. It can be somewhat limiting in terms of their ability to engage in social activities and leave the home. And -- and rarely, in a very small number of cases, it can be threatening -- life-threatening.
For example, if the prolapse is so advanced that the bladder is completely outside the vagina and patients can't pee at all, their bladder just gets bigger and bigger. I mean, that's life-threatening. But that's rare. That's unusual.
Q. And what about in the case of Ms. Smith? Her --her -- her pelvic organ prolapse was not life-threatening. Is that fair?

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A. I don't think it was life-threatening, no.
Q. Are you aware that Dr. Arnaud, who was Gynecare's Scientific Director of Europe, said that because pelvic organ prolapse is a functional disorder and not a life-threatening disease, the treatment for it must not lead to serious complications?
MS. MERK: Object to form.
You can answer.
THE WITNESS: I don't -- I don't recall hearing this quote from this doctor.
BY MR. CANTRELL:
Q. Okay. Do you agree with that statement?
A. Well, I think, in general, any surgery should not lead to serious complications. And I don't think -- I think every surgeon and every patient, when they plan a surgery, is planning on the outcome to be without complications and the outcome to be good. Nobody plans a surgery with complications in mind.
Q. Certainly. But you would agree with me that there is a risk-benefit analysis to take place depending upon the type of injury, the more dangerous or life-threatening it is --
A. Yes.

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Q. -- the more risks that the surgeon and the patient are apt to take with regard to the surgery. Is that fair?
A. Yes.
Q. Okay. And I want to ask you a few additional questions about your training. I believe you mentioned it occurred at Saint Joseph's in Milwaukee in 2005.
A. I did not say Saint Joseph's.
Q. Okay. I'm sorry.
A. I don't recall the name of the hospital we were at. I just remember flying to Wisconsin. I think it was Milwaukee.
And when we were in the airport, there were people wearing funny hats, and they called themselves Cheeseheads, and I had never heard that term before. And I remember ordering a salad at dinnertime, because I wanted to be healthy, and, when it came, they had it in this tall glass, and half of it was cheese. I couldn't believe it.
But I remember being there a weekend. I was there with Dr. Curtis. There was another doctor there. And we watched a few surgeries.
We actually scrubbed. We were in the operating room. And it was a -- There was some

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lecture and some surgery, you know, portion to the training.
Q. Okay. And I want to ask you a few questions about the lecture portion, if I can.
Did you believe that the information that was being presented to you at this Ethicon training would be fair and balanced in the sense that they would tell you both the positive aspects of the Prolift and any negative aspects of it?
A. I think so. I mean, I think -- I think we were all -- always just a little bit skeptical when we were going to training programs put on by the manufacturer, but I think, by and large, yes. And...[pause].
Q. Now, prior to this training seminar, I assume that you had not implanted a Prolift at that point.
A. That's correct.
Q. Had you implanted any type of pelvic organ prolapse kit using synthetic mesh?
A. I believe, prior to that time, we were doing TVTs for stress urinary incontinence.
And I believe we were also doing another vaginal procedure where we -- we had -- or we custom-cut a piece of mesh and then sewed it to a

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synthetic material and then anchored it where the sacrospinous ligaments were.
Q. Okay.
A. I remember, I think, going to Texas, you know, a different manufacturer, and we did training there in cadaver labs. So we had done that.
But when the Prolift became available, it was -- just seemed like a much better product, and the -- the trocars, the guides, the whole system just was more patient-friendly. It just worked a lot better.
Q. And I realize it was a long time ago, but to the extent you have a recollection of it, what do you remember being told about the development of the Prolift?
A. I'm not sure what you mean by "development."
Q. Well, did they discuss with you how it came to be developed? For example, that it was developed by -- in part by a group of French surgeons?
A. I remember something about it being developed by French surgeons. I don't remember too much else.
Q. Okay. Are you aware that, in April 2006,

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those doctors who developed the Prolift procedure told Ethicon that they needed to develop a safer mesh because of problems with contraction and erosion of the mesh, and those discussions were ongoing even actual -- even after the actual launch of the Prolift in 2005?

MS. MERK: Objection.

BY MR. CANTRELL:

Q. Are you aware of that?

A. No.

Q. Would that have been something that you would like to have known in weighing your decision on whether to put the Prolift in your own patients?

A. Yes.

Q. Did anyone at the seminar tell you that the same French doctors who developed the Prolift, as early as 2003 told Ethicon that they were concerned about erosions and contraction associated with the Prolift mesh?

MS. MERK: Objection.

THE WITNESS: No.

BY MR. CANTRELL:

Q. Okay. Again, is that something you would have liked to have known in making your own risk-benefit assessment on whether to use that

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product in your own patients?

MS. MERK: Objection.

THE WITNESS: You know, yes. I think we would be interested in knowing as much information as possible.

BY MR. CANTRELL:

Q. How long after the session was it that -- that you implanted your first Prolift?

A. You know, I don't -- I don't recall exactly.

Q. Okay.

A. I can't recall.

Q. Well, let me -- Maybe I can ask it this way. I know it was a long time ago, Doctor, and it's not a memory test.

But was Ms. Smith your first patient that you implanted --

A. No.

Q. -- Prolift -- Okay.

A. No. I don't think so.

Q. And you mentioned that there became some point in time that you stopped using the Prolift. Is that correct?

A. Right. You know, different technique, you know, this -- the laparoscopic sacral

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colpo-suspension became available, and we gradually went in that direction and did less and less Prolift surgeries.

Q. When was the last time you did the transvaginal implantation of a Prolift?

A. Don't know exactly.

Q. Okay. And I think you gave an estimate of use -- of implanting the Prolift in approximately 25 to 30 of your patients during your career?

A. I believe our group did about 75, you know, Prolift surgeries, something like that. And there were three of us that were doing it. So I figure I did maybe a third or...[pause].

Q. Okay. Do you recall how many of those patients received Prolifts both anteriorly and posteriorly, like Ms. Smith?

A. I can't say.

Q. Okay. Was it the norm, though, that they received Prolift both anteriorly and posteriorly?

A. I did a number that way. I think I did quite a few where I did only the posterior Prolift, but I did a number of total Prolifts. But I -- I can't give you exact numbers.

Q. And I believe your testimony was you stopped using the Prolift and went to this

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laparoscopic approach --

A. Right.

Q. -- because the complication rate is higher with the Prolift transvaginal implantation versus laparoscopic. Is that correct?

MS. MERK: Objection.

THE WITNESS: I think the main reason we sort of went in that direction is that the success rate is higher. The biggest problem with pelvic organ, you know, reconstructive surgery has always been, you know, recurrent prolapse problems.

And we felt that -- In our Prolift patients, we felt that the success rate wasn't quite as good as we'd hoped it would be. We were seeing a little bit more, you know, recurrent prolapse than we wanted to see.

And we felt that the laparoscopic patients, you know -- For a time we were doing both, hand in hand, and then we -- it was our opinion that we just got better results with -- with the laparoscopic approach.

And then we were also seeing, I think, more vaginal mesh erosions than we wanted to see or -- or, you know, that -- so it was a little bit of both, I think.

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BY MR. CANTRELL:
Q. Now, I know were you shown a copy of the FDA advisory in 2008. Are you familiar with a second FDA health advisory in 2011 regarding transvaginal mesh?
A. I believe I saw that also.
Q. Okay. And in that one, they announced that severe complications related to the transvaginal implant plantation of mesh are not rare. Is that your recollection?
A. I think by 2011 we weren't doing Prolifts anymore.
Q. Certainly. Okay. That was my question.
I wanted to try and narrow down the time frame, to the extent possible, to make sure that you had stopped prior to that or was that something that --
A. I remember --
Q. -- precipitated your stopping?
A. I remember that -- that -- When the second FDA announcement came, I remember that -- that our group felt good about going in the direction of laparoscopic, you know, surgeries, and we felt good that we had gone that way and that we weren't doing Prolift anymore.

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Q. And I want to ask you something about -- You mentioned that Mrs. Smith had adhesive disease at the time you implanted the Prolift. Is that correct?
A. So the very first time I saw her, she told us that when she had her hysterectomy, that it took seven hours or something like that, and her surgeon told her that it was like somebody dumped a bucket of glue in her belly and everything was stuck to everything. So that was what she told us at the very first visit.
Q. Okay. But, obviously, the fact that she had that condition or she told you that she had that condition, you didn't feel that made her an inappropriate candidate for the Prolift; is that fair?
A. If anything, that made her a very good candidate for Prolift because, with the Prolift procedure, we do not enter the abdominal cavity.
And the alternative at that time that we were offering patients was a big abdominal incision and using mesh on the inside, and that was -- that was clearly too risky to consider.
So she was an excellent candidate for Prolift. Excellent.

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Q. Now, at this point -- I believe her implantation was in April of 2006 -- there were some surgeons, urogynecological surgeons that were implanting transvaginal mesh laparoscopically at that time; is that correct?
A. Well, transvaginal mesh by definition means you are implanting it vaginally, and -- and I don't think anybody would take a vaginal mesh kit and implant that mesh lap- -- I've never heard of that. So --
Q. Yeah. Forgive me. That was a poorly phrased question. Let me --
A. So the mesh that we implanted laparoscopically was usually something we fashioned out a big piece of mesh. There were some companies that actually had little Y grafts. But we -- we just used the big piece of mesh and cut our own and custom-fitted it to the patient.
Q. My question, though -- and I agree, it was poorly phrased, so forgive me for that -- my question was, at the time of Ms. Smith's surgery in 2006, there were some surgeons that were implanting mesh laparoscopically for the treatment of pelvic organ prolapse. Is that correct?
A. I think -- I don't recall exactly. That

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certainly was not common practice. It was certainly not standard of care. I think some surgeons were experimenting with that a little bit.
Clearly, at that time, that was way beyond our ability. That was not something that was being done at the medical school in Portland. Our program had close ties to the medical school. We tried to, you know, sort of be in step with them and be aligned with them.
Q. And, certainly, that wasn't meant to be any criticism of your --
A. Right.
Q. -- I'm just asking questions. So thank you.
A. And Mrs. Smith would never be a candidate for laparoscopic surgery also because of all the adhesions.
Q. Okay. So in your opinion, she wouldn't be a candidate for laparoscopic surgery either?
A. Laparoscopic surgery would even be much more dangerous than making an open incision. Much more dangerous.
When somebody has lots of adhesions, we favor a laparotomy where we make a big incision over a laparoscopic approach.

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Q. I'm going to ask you a couple of questions about the informed consent --
A. Okay.
Q. -- page that was in the medical records there, if you would get that. I believe it was --
A. All right.
MS. MERK: 3.
BY MR. CANTRELL:
Q. Let me see which page it was.
A. Looks like it's 820. Is that the page you are referring to?
Q. I think that's right.
Now, the form itself doesn't specify exactly what risks that you told Ms. Smith other than mentioning the -- what is it, the PA -- PARQ discussion?
A. Right. That's correct.
Q. Okay. And you don't have an independent recollection, sitting here today, of your conversation with Ms. Smith 11 years ago, do you?
A. I do not.
Q. Okay. So your testimony about what conversation you had with her about your risk is just based on your -- your recollection of what you generally do in these cases; is that fair?

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A. That's correct.
Q. Okay. And it would also be fair to say that your discussion with Ms. Smith at that time was based upon the risks and complications that you were aware of in 2006 relative to the Prolift; is that fair?
A. Yes, that's correct also.
Q. And I want to ask you a couple questions about the -- the erosion surgery that you performed on Ms. Smith. I think -- We don't have the op report in there, but I think it was referenced on the -- 549.
A. 549.
Q. And I recognize that we don't have the op report, but if you wouldn't mind just telling the jury in kind of general detail what that surgery would entail.
A. So we don't have the operation report. You know, it was my custom to dictate an op note when I -- so in a situation like this, you know, we -- I always did cystoscopy with this procedure. Sometimes I did it first just to establish that everything was normal in the bladder, and then I did it a second time at the conclusion of the surgery.

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So in general, the patient was started under general anesthetic. We generally, I think, only rarely used a regional anesthetic. And then the patient was positioned so that we had access to that area.
And then we would put retractors inside, and this was all after the nurses prepped her with antimicrobial, you know, preparation soaps, and then retractors were placed inside, and then a careful examination was made.
Because the examination in the office is always somewhat limited because it's always uncomfortable for the patient. So in the operating room, when we had anesthesia, we can do a much, much better examination.
So the first thing we do is always a very, very careful examination to make sure there aren't any other places where there is mesh erosion. Sometimes mesh erosion occurs in multiple places.
And then, once we have determined, you know, the extent of the problem, then what we generally do is we infiltrate the vaginal epithelium with a dilute solution of a local anesthetic agent containing epinephrine. The epinephrine constricts blood vessels and minimizes

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bleeding. And it's not that there is a great deal of blood loss with this, but -- but by minimizing the bleeding, it keeps the operative field cleaner and we can see better.
And then, using sharp dissection, using a scalpel, using scissors, we basically sort of undermine the normal vaginal skin around the mesh. We then excise the mesh. And then we put in a few stitches to pull the skin together again without tension and then -- so it has a chance to heal.
Q. Okay. And just to give the jury a picture of this, when -- is -- The patient, I would assume, is placed in a supine position and her legs in stirrups. Is that correct?
A. That's correct.
Q. Okay. And then you would enter vaginally to excise --
A. That's correct --
Q. -- the mesh --
A. -- this is all done vaginally. And then, when the patient wakes up, she really has very, very minimal pain from this and very, very minimal discomfort.
This is an outpatient surgery. It usually takes an hour or less, you know.

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Q. Now, how is it excised? With scissors? A scalpel?
A. Yes.
Q. Which one? I'm sorry, Doctor.
A. Both.
Q. Both. Okay.
A. So the initial incision I usually made with a scalpel, and then I finished it with Metzenbaum scissors.
Q. Now, it would be -- and again, I recognize we don't have the op report -- but it would be typical in that situation for you to send the -- any explanted material to pathology. Is that correct?
A. Always. That was our routine.
Q. And I will represent to you that you did. I mean, we have the operative report. I'm not sure why we don't have it here today, but that's okay. You did do that in this circumstance, I'll represent to you.
In your medical opinion, was this surgery to remove the eroded mesh medically necessary?
A. Yes.
Q. If I represented to you that the final pathologic diagnosis for this mesh said:

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"The mesh caused an inflammatory reaction in Ms. Smith's vagina and that was a foreign body giant reaction,"
what does that mean?
A. Well, whenever there is an injury or foreign body or anything, there is always an inflammatory reaction. That's very, very common in path reports.
So when you tell me those terms, that basically just tells me that this was, you know, a synthetic material and this was how her body was sort of handling this, dealing with this.
Q. So is it fair to say it's the body's reaction to a permanent implant like the Prolift?
A. Yes.
Q. Would it surprise you to know that Ms. Smith had another surgery in August 2012 to repair two additional eroded areas of mesh as well as chronic abscesses?
MS. MERK: Objection.
THE WITNESS: I'm sorry. I was coughing. Can you repeat that?
BY MR. CANTRELL:
Q. Certainly, Doctor. I was just asking would

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it surprise you to learn that Ms. Smith had an additional surgery in August of 2012 to repair two additional areas of eroded mesh from the Prolift as well as chronic pelvic abscesses?
MS. MERK: Objection.
THE WITNESS: I guess I am a little surprised, you know.
BY MR. CANTRELL:
Q. Yeah. And she was hospitalized for almost two weeks for that procedure. Would that surprise you, as well?
MS. MERK: Objection.
THE WITNESS: Yes, it would.
BY MR. CANTRELL:
Q. Okay.
A. I haven't heard from her in a long time.
Q. Certainly. I think that was the last --
A. And by and large, you know, every visit that I had with her was friendly, amicable. I seem to recall her being -- laughing and cheerful.
And, you know, sometimes patients change insurance. You know, it's always kind of a mystery to me why she -- I didn't see her back again and --
But, you know, developing abscesses, that's something that I told -- that's -- that can

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happen after any surgery, and it's more common when you put a mesh in somebody, whether you do it abdominally, through a laparotomy, or laparoscopically or vaginally.
Q. Let me ask you this. You mentioned that you thought that could be something you told her back in 2006.
How did you know that was a risk or complication of the mesh back in 2006?
A. Well, you know, we had been doing mesh surgeries for many years where we made a big abdominal incision and put mesh inside. And some of those patients developed, you know, abscesses and were very sick and were sometimes in the hospital for a week or two after surgery. So we had experience with that.
And there was no reason to think that putting mesh in a patient transvaginally instead of abdominally, and we're almost in the same area, couldn't lead -- couldn't occasionally lead to the same -- you know, a similar problem.
Q. Okay. Do you recall --
A. In general, I tried to -- You know, in general, I tried to always paint kind of a bad picture, you know. It was sort of like -- like --

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like talk about every complication, talk about the worst, talk about everything, you know, sort of prepare for the worst and hope for the best, you know, when I did informed consents.

Q. Okay. Do you recall if, at this training seminar in 2005, someone from Ethicon told you that that kind of chronic pelvic abscess could result from the Prolift implant?

MS. MERK: Objection.

THE WITNESS: I don't recall.

BY MR. CANTRELL:

Q. Okay. And I know we talked about this a few minutes ago, about the FDA health advisory in 2011, and you said you had some vague recollection of that or some recollection of that.

A. (Witness moves head up and down.)

Q. Are you aware that the FDA at that time recommended that any surgeon considering implanting mesh transvaginally for the treatment of pelvic organ prolapse informed patients that the implantation of the mesh is permanent and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication?

A. So you are asking me if I was aware of

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that?

Q. Yes.

A. Yes.

Q. Okay. Are you aware that they also determined that in most cases pelvic organ prolapse can be treated successfully without mesh, thus avoiding the risk of mesh-related complications?

A. And, you know, it was our practice to always really, really encourage patients to try nonsurgical things first. So with Mrs. Smith, we tried pessaries, we tried physical therapy, we tried hormone therapy, you know, with the estrogen.

And -- and she was the one that didn't want to try another pessary. She was the one who didn't want to do physical therapy. Our nurses were sort of, like, really strong proponents of -- of using pessaries. Our clinic, probably more than other -- any other in the City of Portland probably had the biggest selection of pessaries in the clinic, you know, fitting pessaries and others. We probably fit more -- fitted more patients with pessaries than anybody else.

And in our setting in Kaiser, which is an HMO, it's very different than private practice. In private practice, when a doctor does surgery, they

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get paid a lot of money. When I did surgery, I didn't get paid anything extra. And if anything, there was just more risk and more work. You know, I had to come in earlier and do rounds, I had to come in -- I had to stay later. There was really no incentive for us to do unnecessary surgery.

And it was Mrs. Smith who was really pushing for surgery. Our staff, we would have gladly treated her longer nonsurgically.

Q. Oh, I understand that. And I appreciate you discussing the nonsurgical treatments that were available.

But let's focus on the surgical treatments available. The implantation of transvaginal mesh was not the only surgical option available for the treatment of pelvic organ prolapse at that time, was it?

A. That's correct.

Q. There were other surgical options available, such as native tissue repair?

A. That's correct.

Q. There were biologic grafts available at that time; is that correct?

A. That's correct.

Q. And I want to go back and talk a little

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more about the 2011 FDA health advisory and the subsequent committee determinations made by them.

Are you aware that they determined that the risk of transvaginal mesh for the treatment of POP outweighed benefits and that it should be used only as a matter of last resort?

MS. MERK: Objection.

THE WITNESS: I remember reading that. And in 2011, we weren't using transvaginal mesh anymore. Unless you consider TVTs and TOTs, you know -- I mean, those would be the only transvaginal mesh surgeries we were doing at the time.

BY MR. CANTRELL:

Q. Certainly. But those are for the treatment of stress urinary incontinence and not pelvic organ prolapse; correct?

A. That's correct.

Q. Do you have any reason to disagree with that statement from the advisory committee?

A. I do not.

Q. Okay.

A. They have lots of experts that they use, and I -- I have no reason to disagree with that.

Q. At the time you implanted the Prolift in

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Ms. Smith, was it your understanding that the Prolift had been approved by the FDA for the treatment of pelvic organ prolapse?
A. Yes.
Q. Did someone from Ethicon tell you that it was FDA-approved?
A. Yes.
Q. Okay. Would you be surprised to learn that that's not true?
MS. MERK: Object to the form.
THE WITNESS: Yes, I would.
BY MR. CANTRELL:
Q. Okay. It wasn't FDA-approved until 2008 --
MS. MERK: Object to the form.
BY MR. CANTRELL:
Q. -- by the FDA. Were you aware of that?
MS. MERK: Same objection.
THE WITNESS: No.
BY MR. CANTRELL:
Q. Now, given that knowledge, that it was not FDA-approved at the time of 2006, would you have still implanted a non-FDA-approved medical implant in Ms. Smith?
MR. CANTRELL: Objection.
THE WITNESS: Quite possibly. I mean, in

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medicine, lots of things that are -- are done that are not FDA-approved and -- whether it's using medications, you know, like Terbutaline to stop labor.
There's a big, expensive process to get FDA approval, and -- and if there is a large body of medical evidence, you know, suggesting that something is safe and effective and that's in common use, even if it's not FDA-approved, you know, that can be the standard of care in medicine.
BY MR. CANTRELL:
Q. Would it be fair to say, though, that you would have relayed that to Ms. Smith that you were using a non-FDA-approved implant in her at the time of her surgery so she could weigh that into her determination --
A. I think I would have, yeah.
Q. And the things you talked about, for example, the medication, I think, you mentioned -- and I'm not going to try and pronounce it -- that's what we would call off-label use; correct? Meaning it's approved by the FDA for one use, but it may have --
A. Yes.
Q. -- you know, value in some other use;

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correct?
A. Yes.
Q. Okay. But that's not what we are talking about here.
The Prolift at this time had not been approved for any reason by the FDA.
A. (Witness moves head up and down.)
Q. So I'm going to ask you that question one more time. Given that knowledge, would you still have implanted that into Ms. Smith?
MS. MERK: Objection.
THE WITNESS: I don't know. Maybe, maybe not. I don't know.
BY MR. CANTRELL
Q. That's fair enough, Doctor. That's fine.
I don't have anything further at this time. I may have some additional questions after rebuttal.
MS. MERK: Could we go off the record for a minute?
THE VIDEOGRAPHER: The time is now 11:21. We are going off the record.
(Off the record.)
THE VIDEOGRAPHER: The time is now 11:22, and we are back on the record.

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REEXAMINATION
- - -
BY MS. MERK:
Q. Doctor, you testified about the different approaches that you used as time went on and that you would use a piece of mesh that you cut and customized for your patient. What mesh product would you use?
A. As far as I know, we used Gynemesh, the exact same mesh that was used in Prolift and TVTs and TOTs.
Q. And did your experience with Gynemesh enter into your risk-benefit analysis when deciding to use the Prolift product in Mrs. Smith?
A. Yes. We had -- we had a lot of history, a lot of experience with Gynemesh. And that was a big improvement over the meshes that we used before that.
Q. Putting yourself back at the time that you implanted in Ms. Smith, but knowing what you know now, do you agree that Prolift was a safe and effective treatment for her?
A. I think -- I think -- Since, you know, her surgery, I think we have perhaps appreciated

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that the risk of mesh exposure is greater than we thought at that time.

And -- and -- and then, again, you know, Mrs. Smith was noncompliant. She didn't use the estrogen vaginally. I think that's a big factor. I think that's a big reason why she had so many problems.

And the other issue is that she was a smoker. I believe she stopped in 2008, but she was a smoker. And smokers have many more problems with -- or their risk of mesh exposure is greater. And that's something I think we didn't understand as well in 2006 either.

Q. Fair to say that medicine generally evolves as you learn more?

A. Yes. It's always evolving. I tell people that the questions are always the same, it's just the answers that change in medicine.

MS. MERK: I have no further questions, Doctor. Thank you.

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REEXAMINATION

- - -

BY MR. CANTRELL:

Q. I just have one quick question, Doctor, I

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neglected to ask you earlier, when we were talking about her estrogen use.

Now, the estrogen, you think it may have had -- played a role in the erosion that she suffered from. Now, that estrogen was prescribed after you discovered the erosion; is that correct?

MS. MERK: Objection.

THE WITNESS: It was -- it was prescribed after her first surgery. We prescribe that for everybody after pelvic reconstruction surgery, with mesh and without mesh, in everybody.

This was something that our group of urogynecologists felt was very, very important. There was -- there were lots of evidence in the literature that -- that showed that -- that the connective tissue stayed stronger in women longer who used estrogen, and it quickly became weaker if they failed to use vaginal estrogen. So we recommended it in everybody. We felt it was very safe and...[pause].

We perhaps increased the frequency of use, you know, so -- so, after surgery, we might recommend it two or three times a week. And if somebody has a mesh erosion, we might recommend it every -- you know, daily. But it's recommended in

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everybody from their first surgery.

Even before surgery. We like to start it before surgery.

BY MR. CANTRELL:

Q. Okay. Now, in -- One of the things you check when do you an exam -- a vaginal exam of a patient, you confirm whether their vaginal cavity is sufficiently -- estrogenized? Is that a proper term? Is that correct?

A. (Witness moves head up and down.)

Q. Is there any indication in your notes there -- and if there isn't, perhaps I -- perhaps there isn't, I didn't see it -- that her vaginal cavity was not sufficiently estrogenized?

A. You know, this is very subjective, and she was sixty, I think, four when she had her first surgery. Sixty-four is in the menopausal period. Everybody has some atrophy when they are 64.

And, you know, if somebody is severely atrophic, you know, we might postpone their surgery. We might not do surgery and instead might put them on estrogen therapy for several months.

I think, in her case, that wasn't -- she didn't have severe atrophy, but she had some atrophy, which was normal for a 64-year-old.

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MR. CANTRELL: Okay. Nothing further.

MS. MERK: Nothing further.

THE VIDEOGRAPHER: The time is now 11:27. This concludes the deposition. We are going off the record.

THE REPORTER: Do you do any signature stipulation?

MS. MERK: It's up to you. You have the option of reviewing the transcript for accuracy and signing it or you can waive it.

THE WITNESS: I can waive that.

(The deposition concluded at: 11:28 a.m.)

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CERTIFICATION

I, Karen I. Pearson-Bell, Certified Shorthand Reporter, in and for the State of California, do hereby certify under the laws of the State of California:

That the witness named in the foregoing deposition was, before the commencement of the deposition, duly administered an oath in accordance with the California Code of Civil Procedure Section 2094; that the testimony and proceedings were reported stenographically by me and later transcribed into computer-aided transcription under my direction; that the foregoing is a true record of the testimony and proceedings taken at that time.

IN WITNESS WHEREOF, I have subscribed my name this 1st day of February.

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Karen I. Pearson-Bell, RPR, CSR No. 3557

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ERRATA

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LAWYER'S NOTES

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